DEPARTMENT OF HEALTH AND HUMAN SERVICES

95124d

Food and Drug Administration
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

December 8, 2004

WARNING LETTER NO. 2005-NOL-04

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Joann G. DeFriese, Owner
Continental Caviar
1190 Cross Creek Drive
Franklin, Tennessee 37067-4032

Dear Ms. DeFriese:

On September 28-29, 2004, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility, located at 1190 Cross Creek Drive, Franklin, Tennessee. Our findings revealed serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and Food Labeling regulations in 21 CFR 101. You may find the Federal Food, Drug, and Cosmetic Act (the Act) and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products **adulterated** under Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4). Accordingly, your paddlefish roe is adulterated because it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

The Seafood HACCP deviations are as follows:

- To comply with 21 CFR 123.11(b), you must adequately monitor sanitation conditions and practices during processing with sufficient frequency to ensure sanitation control. Your firm did not monitor the safety of water coming into direct contact with food or food contact surfaces, including water used to manufacture ice; condition and cleanliness of food contact surfaces; prevention of cross-contamination from unsanitary objects; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration; proper labeling, storage and use of toxic chemicals; control of employee health conditions; and, exclusion of pests.

- You must maintain sanitation control records documenting, at minimum, the monitoring and corrections to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation

monitoring records for the safety of water coming into direct contact with food or food contact surfaces, including water used to manufacture ice; condition and cleanliness of food contact surfaces; prevention of cross-contamination from unsanitary objects; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration; proper labeling, storage and use of toxic chemicals; control of employee health conditions; and, exclusion of pests.

- You must have and maintain records which fully document all corrective actions taken to comply with 21 CFR 123.7(d). Specifically, your firm destroyed [redacted] pounds of thawed paddlefish roe as a result of a freezer malfunction on March 24, 2004; however, your firm failed to document the corrective action.

Your repackaged caviar product is misbranded under Section 403 of the Act as follows:

- The product labeled as "AMERICAN CAVIAR GRAY PEARL PADDLEFISH" is misbranded under Section 403(i)(2) of the Act because it fails to declare accurately the fish roe ingredient by its common or usual name in the ingredient list, as required by 21 CFR 101.4(a). The product is also misbranded under Section 403(a)(1) of the Act because the product bears false or misleading labeling. During our inspection, the investigator observed this product is repacked from a bulk container labeled as containing "Paddlefish Roe & Salt." However, the ingredient list on your repackaged product falsely identifies the fish roe ingredient as "STURGEON ROE."

- The product is also misbranded under Section 403(e)(1) of the Act because the label does not identify correctly the name and place of business of the manufacturer, packer, or distributor, as required by 21 CFR 101.5(a) and (d). Your current location of business operations is Franklin, Tennessee, not Chattanooga, Tennessee as declared on the label, and the name of your firm is "Continental Caviar" rather than "CONTINENTAL CAVIAR OF AMERICA."

  The common or usual name and place of business deviations were brought to your attention in our letter to your firm on July 16, 2003.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. You should include in your response documentation, such as a revision of your seafood HACCP plan, sanitation control records, corrective action records, and a copy of your revised finished product label, or other useful information that would assist us in evaluating your corrections. If you cannot complete corrections within 15 working days, we expect you to explain the reason for the delay and state when any remaining deviations will be corrected.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, Seafood HACCP regulations, and Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, Tennessee 37217. If you have questions regarding any issue in this letter, please contact Ms. McMillan at (615) 781-5380 x138.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

Enclosure: Form FDA 483
Labeling regulations 21 CFR 101.4 & 101.5
Fish & Fishery Products regulations 21 CFR 123